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adding bulking agent to the solution, and

sterile filtering, dispensing into injection vials and lyophilizing the solution,

thereby obtaining a sterile Cetrorelix lyophilizate.

Please cancel claim 24, without prejudice.

II. REMARKS

Preliminary Remarks

This response is timely filed as it is accompanied by a petition for an extension of time to file in the first month and the requisite fee. Attached is a marked-up version of the changes made to the specification and claims by the current amendment. The attached Appendix is captioned **"Version with markings to show changes made"**.

Entry of the foregoing amendment is requested pursuant to 37 C.F.R. §1.116 in that the amendment to claim 20 complies with the examiner's comments in the final official action and further, that the amendment to claim 20 now places the application in a condition for allowance.

35 U.S.C. §103(a)

The examiner again rejected claims 20-23 (and further included claim 24) as allegedly being unpatentable over Wolfe *et al.* in view of Behre *et al.*, essentially for the reasons stated in the prior official action.

The applicants respectfully traverse. Specifically the applicants submit that the cited documents either alone or in combination do not teach or suggest that applicants' claimed invention as defined by amended claim 20 and claims 21-23. Although Wolfe *et al.* discloses a method for the production of lyophilized LHRH, the applicants method require the use of a specific decapeptide and specific pH of acetic acid to produce the Cetrorelix lyophilizate.

Berhre *et al.* does not ovecome the deficiences of Wolfe *et al.* Specifcally, while the cited document teaches that Cetrorelix is an antagonistic analog of GNRH and further discloses that lyophilized Cetrorelix is dissolved in water containing mannitol for injection, as with Wolfe *et al.*, the cited document simply neither teaches nor suggest the applicants' claimed invention.

For the reasons stated above, Wolfe *et al,* either alone or in combination with Behre *et al.* neither teach nor suggest the applicants' claimed invention. Therefore, the applicants request that the rejection of claims 20-23 under 35 U.S.C. §103(a) over the cited documents be withdrawn.

III. CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action is hereby solicited. If any point remains in issue that the examiner feels may be best resolved through a personal or telephone interview, the examiner is **strongly urged** to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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Enclosure: Appendix

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claim 20 was amended as follows.

20. (Amended) A method for the preparation of a sterile Cetrorelix lyophilizate, said method comprising the steps of

dissolving Cetrorelix having the amino acid sequence of

AC-D-Nal(2)-D-pCl-Phe-D-Pal(3)-Ser-Tyr-D-Cit-Leu-Arg-Pro-D-Ala-NH_2

in aqueous acetic acid to form a solution, wherein the acetic acid has a pH range between 2.5-3.0,

diluting said solution with water for injection,

adding bulking agent to the solution, and

sterile filtering, dispensing into injection vials and lyophilizing the solution,

thereby obtaining a sterile Cetrorelix lyophilizate.

Claim 24 was canceled, without prejudice.

End of Appendix